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Defending Local Working

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Defending Local Working

DEFENDING LOCAL WORKING

*Melat Arega**

ABSTRACT

The trade-off between the private interests of the patent holder and the public interests of society is largely recognized as the basis for the development of a patent system of laws. In exchange for protecting the inventions of patent holders in the marketplace, patent law also provides governments with certain flexibilities to ensure the monopoly power granted by patents is not abused, or negatively affects the economy, and the general public interest. One of the flexibilities afforded to countries is the compulsory license. One of the criteria long recognized for granting such a compulsory license has been the failure to meet “local working” requirements. Denying the public access to patented inventions halts innovation, and worse even, in the case of medicines, cost lives. Currently, there is a new move to limit the availability of a working requirement in developing countries through trade negotiations. This new move raises an old question: whether local working grounds for issuing compulsory licenses follows TRIPS obligations? This was left unanswered in large part due to the absence of a definitive stance by the WTO and varying interpretation of the Paris Article 5 (A) and TRIPS Article 27.1. This article will introduce the history of working requirements; perform a legal analysis of the TRIPS legality of local working requirement; and finally, propose a balanced approach to working requirements that could be used in future negotiations.

* American University Washington College of Law, J.D. 2018; Bridgewater College, B.S. Biology. I would like to thank Sean Flynn, Associate Director, Program on Information Justice and Intellectual Property Professorial Lecturer in Residence, and Hendricks Valenzuela for their work in developing this article.

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INTRODUCTION

This article seeks to establish that domestic policies that grant a compulsory license to a local producer when a patentee has failed to meet “local working” requirements are in accordance with the Agreement on Trade-Related Aspects of Intellectual Property (“TRIPS”).¹ A patent is a property right that gives an inventor the legal rights to prevent others from making, using, or selling an invention for a period of time.² It is one of the oldest methods of intellectual property protection and it is aimed at the protection of rights and development of innovation. Patents are used to increase investment in research and development (“R&D”) and innovation.

TRIPS is defined as the most “comprehensive multilateral agreement on intellectual property” and imposes certain requirements on WTO members to provide intellectual property protection within their domestic legislation.³ The agreement is meant to provide stability in the international trade arena.⁴

TRIPS was negotiated as part of the Marrakesh Agreement Establishing the World Trade Organization (“WTO Agreement”) and is aimed to set out “minimum standards of protection to be provided by each Member,” with certain exceptions.⁵ Like many intellectual property regimes, this agreement is based on the fundamental principle of promoting the progress of science, innovation, and useful arts.⁶

The minimum standards of TRIPS have been applied in a manner which limits the flexibilities originally granted to developing countries.⁷ In particular, broad interpretations of Article 27 (1)⁸ are used to achieve such limitations. One of the

¹ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

² Janice Mueller, *PATENT LAW* (Aspen Student Treatise Series, 5th ed. 2016).

³ See WTO, *Overview: The TRIPS Agreement*, WORLD TRADE ORGANIZATION https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Apr. 4, 2019).

⁴ See *id.*

⁵ See Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994) [hereinafter Marrakesh Agreement]; *Overview: The TRIPS Agreement*, *supra* note 4.

⁶ See generally Peter K. Yu, *The Objectives and Principles of the Trips Agreement*, 46 Hous. L. Rev. 979, 982-83, 1000 (2009) (describing the negotiation process for the TRIPS Agreement).

⁷ See Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 Yale L.J. 804, 820 (2008) (“IP rights have become significantly stronger over the past thirty years, in both the domestic and international realms”); see also Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 Tex. L. Rev. 1031, 1042 (2005) (“By virtually any measure, intellectual property rights have expanded dramatically in the last three decades”); see, e.g., Ellen F.M. ’t Hoen, *THE GLOBAL POLITICS OF PHARMACEUTICAL MONOPOLY POWER* 37 (AMB Publishers, 2009).

⁸ TRIPS, *supra* note 2, at 331-32. The full text of TRIPS Article 27 states:

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70

flexibilities currently in question is the right of States to grant compulsory licenses⁹ due to a lack of “local working.”¹⁰ This flexibility is meant to prevent abuses of the monopoly power granted by patents.

The availability of compulsory licensing is imperative to developing States in formulating a proper balance to achieve specific national interests. This balance must also maintain an incentive to invent for patent holders. The incentive encourages pharmaceutical companies to invest in the R&D of new, possibly life-saving medicines.¹¹ This article will argue for recognition of the right and take it a step further by proposing how they should be defined in order to maintain the balanced approach, which advocates on both aisles of the dispute recognize as the correct way to interpret patent law.¹²

and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

⁹ *Compulsory Licensing of Pharmaceuticals and TRIPS*, WORLD TRADE ORGANIZATION (Mar. 2018), https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

(“Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself. It is one of the flexibilities in the field of patent protection included in the WTO’s agreement on intellectual property — the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement.”).

¹⁰ See Prity Khastgir & Rahul Dev, *Local Working Requirements and Enforceability of Patents: an Indian Perspective of Challenges and Opportunities Surrounding a Granted Patent*, ASIA PAC. REGIONAL F. NEWS (Int’l Bar Ass’n), Aug. 2011, at 23 (referencing local working as the condition imposed by a government that a patent owner must make the patented product available in the patent granting country).

¹¹ See Tim Wilsdon, et. al., *Policies that Encourage Innovation in Middle-Income Countries*, Charles River Associates 64 (2012) (“Thus a recent study developed by the OECD attributes part of the success of the pharmaceutical sector of India, China and Brazil to the introduction of product patent protection.”).

¹² See Thomas Cottier, et. al., *Use it or Lose it? Assessing the Compatibility of the Working Requirements in the Paris Convention & TRIPS*, 17 (2) J. Int. Econ. L. 437, 438 (2014) (referring to the “‘intelligent’ balance between the interests of patentees and the community”); Lemley, *supra* note 7, at 1032 (pointing to attempts to “strike an appropriate balance between control by inventors and creators and the baseline norm of competition”); see also Wilsdon, et. al., *supra* note 12, at 64 (pointing to the positive relationship between strengthening protections for intellectual property and economic growth and innovation in middle-income countries).

II. HISTORICAL BACKGROUND

A. *The Vienna and Paris Conventions*

The Vienna Convention on the Law of Treaties¹³ (“Vienna Convention”) is a set of laws and procedures for the making, operation, and termination of a treaty.¹⁴ TRIPS’ Dispute Settlement Understanding (“DSU”) requires interpretation of the agreement to be in accordance with “customary rules of interpretation of public international law.”¹⁵ Vienna Convention Article 31(3)(c)¹⁶ states those customary rules used to interpret international treaties.¹⁷ Article 31 of the Vienna Convention states that a treaty shall be interpreted: (a) in good faith, (b) in accordance with the ordinary meaning to be given to the terms of the treaty, (c) in their context; and (d) in the light of its object and purpose.¹⁸

The Paris Convention for the Protection of Industrial Property¹⁹ (“Paris

¹³ See Anthony Aust, *Vienna Convention on the Law of Treaties* (1969), Oxford Pub. Int’l L., June (2006) (referencing scope of the Vienna Convention on the Law of Treaties).

¹⁴ *Id.*

¹⁵ See *Understanding on Rules and Procedures Governing the Settlement of Disputes*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/dispu_e/dsu_e.htm.

¹⁶ Vienna Convention on the Law of Treaties art. 31, Apr. 24, 1970, 8 I.L.M. 679, [hereinafter Vienna Convention] states,

1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose

2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:

(a) any agreement relating to the treaty which was made between all the parties in connexion with the conclusion of the treaty;

(b) any instrument which was made by one or more of the parties in connexion with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.

3. There shall be taken into account, together with the context:

(a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;

(b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;

(c) any relevant rules of international law applicable in the relations between the parties.

¹⁷ See Campbell McLachlan, *The Principle of Systemic Integration in Treaty Interpretation and Article 31(3)(c) of the Vienna Convention*, 54 Int’l & Comp. L. Q. 279, 290 (2005) (indicating rules of international law must be firmly established and might include custom, general principles, and where applicable, other treaties).

¹⁸ See Susy Frankel, *The WTO’s Application of “The Customary Rules of Interpretation of Public International Law” to Intellectual Property*, 4 Victoria U. Wellington Legal Res. Papers, no. 1, 2014, at 1, 15 (stating that “The WTO has confirmed that it need not apply other rules of international law if applying 31(1) provides the answer. In particular, supplementary material, such as travaux préparatoires, is not the first port of call to illuminate the context. A proper approach to interpretation should only consider supplementary material in the circumstances set out in Article 32 of the Vienna Convention”).

¹⁹ See Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828

Convention”) was adopted in 1883 and enabled inventors to obtain protection for their intellectual creations in the form of industrial property rights such as: patents, trademarks, industrial designs, utility models, service marks, trade names, geographic indications, and the repression of unfair competition.²⁰ This agreement was the first of its kind to protect intellectual property rights in the international setting.²¹

The provisions of the Paris Convention had three main parts to it: national treatment, right of priority, and common rules.²² With respect to protection of industrial property, the provisions on national treatment mandated Contracting States to grant the same protection to nations of other Contracting States as it grants its own nationals.²³ The right of priority provision allows applicants who filed a patent application in one Contracting State first to file for protection in any of the other Contracting States.²⁴ The agreement also lays down a few common rules that all Contracting States must follow; the main ones relate to patents and other issues.²⁵

Paris to TRIPS:

The World Intellectual Property Organization (WIPO) was the main administrator of the Paris Convention. When the agreement was revised in the 1980s, it was seen to have lacked full incorporation of developed nations’ interests. As a result, developed

U.N.T.S. 305 [hereinafter Paris Convention].

²⁰ *Id.*

²¹ *Id.*

²² *See id.* art. 2; *see id.* art. 3; *see id.* art. 4.

²³ *See id.* art. 2.

²⁴ *See id.* art. 4.

²⁵ Paris Convention at art. 3. Full text of Paris Convention Article 3 reads,

(a) Patents. Patents granted in different Contracting States for the same invention are independent of each other: the granting of a patent in one Contracting State does not oblige other Contracting States to grant a patent; a patent cannot be refused, annulled or terminated in any Contracting State on the ground that it has been refused or annulled or has terminated in any other Contracting State.

The inventor has the right to be named as such in the patent.

The grant of a patent may not be refused, and a patent may not be invalidated, on the ground that the sale of the patented product, or of a product obtained by means of the patented process, is subject to restrictions or limitations resulting from the domestic law.

Each Contracting State that takes legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exclusive rights conferred by a patent may do so only under certain conditions. A compulsory license (a license not granted by the owner of the patent but by a public authority of the State concerned), based on failure to work or insufficient working of the patented invention, may only be granted pursuant to a request filed after three years from the grant of the patent or four years from the filing date of the patent application, and it must be refused if the patentee gives legitimate reasons to justify this inaction. Furthermore, forfeiture of a patent may not be provided for, except in cases where the grant of a compulsory license would not have been sufficient to prevent the abuse. In the latter case, proceedings for forfeiture of a patent may be instituted, but only after the expiration of two years from the grant of the first compulsory license.

countries, led by the United States, adopted a trade-based approach, and proposed the inclusion of Intellectual Property Rights (IPRs) within the agenda of the General Agreement on Tariffs and Trade (GATT).²⁶ The Uruguay round of negotiations on TRIPS was launched as part of the Ministerial Declaration of 1986.²⁷ The goal was to establish a multilateral binding agreement that would set minimum levels of protection and enforcement for IPRs.²⁸ This was done so by replacing WIPO's IPRs regimes with a more robust multilateral regime that sets minimal standards for IPRs' protection.²⁹ When the World Trade Organization was established, TRIPS was signed into effect at the Marrakesh ministerial meeting in April 1994.³⁰

B. The TRIPS Agreement

TRIPS is the most comprehensive multilateral agreement on intellectual property that imposes certain requirements on WTO members to provide intellectual property protection within their domestic legislations.³¹ It is meant to provide stability in the international trade arena. It is to date, the most comprehensive multilateral agreement on intellectual property. TRIPS, like many other intellectual property regimes, is based on the fundamental principle of promoting the progress of science, innovation, and useful arts.³² But unlike many of the other negotiations during the Uruguay round, the TRIPS negotiations were focused not on freeing trade, but on changing the domestic regulatory and legal regimes in developing countries.³³

However, when TRIPS was negotiated, it was based on incomplete information.³⁴ Due to the vast gaps in knowledge and negotiation resources between developed and developing countries, the agreement was seen to be an imperfect bargain for developing countries.³⁵ The "constitutional like" governing principles of TRIPS dictates rules to all Member States, whether developed, developing, or least-developed, regarding what

²⁶ Daniel J. Gervais, *The Internationalization of Intellectual Property: New Challenges from the Very Old and the Very New*, 12 Fordham Intell. Prop. Media & Ent. L.J. 929, 943 (2002).

²⁷ See WTO Legal Texts, WORLD TRADE ORGANIZATION, https://www.wto.org/english/docs_e/legal_e/legal_e.htm

²⁸ *Id.*

²⁹ See *Id.*

³⁰ See Marrakesh Agreement, *supra* note 6.

³¹ See TRIPS, *supra* note 1.

³² See, e.g., *Current issues in intellectual property*, World Trade Organization, https://www.wto.org/english/tratop_e/trips_e/trips_issues_e.htm

³³ Bernard M. Hoekman & Michel M. Kosteckl, *The Political Economy of The World Trade System* 283, 284 (2nd ed. 2001).

³⁴ See Daniel Gervais, *Intellectual Property Trade and Development* at 10 (2007) (discussing the conception of the TRIPS agreement).

³⁵ *Id.* at 12.

they must do as members of the WTO.³⁶

However, TRIPS left room for flexibilities in determining methods of protecting products' definition, ownership, management, and expectation.³⁷ The agreement permits Members to enact special or limited exceptions to the exclusive rights granted to the right holders in Article 13 and Article 30 of the agreement.³⁸ Exceptions set out by Member States should not conflict with normal exploitation of the patent holder and should not unreasonably prejudice the legitimate interest of the right holder.³⁹

³⁶ WTO Dispute Settlement, *Rules of Conduct for the Understanding on Rules and Procedures Governing the Settlement of Disputes*, WT/DSB/RC/1 (96-5267) (1996), https://www.wto.org/English/tratop_e/dispu_e/rc_e.htm

³⁷ TRIPS, *supra* note 1, at art. 1.1 ("Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.").

³⁸ *Id.* at art. 13. Article 13 of TRIPS states: "Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder." *Id.* at art. 30.

Article 30 of TRIPS states: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

³⁹ *Id.* at art. 31. Article 31 of TRIPS states:

Where the law of a Member allows for other use (7) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial

The primary objective of TRIPS is "to reduce distortions and impediments to international trade."⁴⁰ Although TRIPS recognizes the need to provide adequate IPR standards, it still needed to balance the interest of accessing information and technology with that of the inventors in the return on their investment.⁴¹ TRIPS sets minimum IPR standards, but the implementation of those standards are left to Members' own discretion.⁴² To avoid distortion of international trade, TRIPS needs to balance the competing interests mentioned above.

TRIPS attempts to induce innovation and increase knowledge sharing. The agreement makes an explicit reference to "the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge."⁴³ An avenue to achieve this goal is through the flexibilities available, all nowing nations to carve out exceptions to protect their citizens.

The Post-TRIPS Era:

TRIPS was unique of its kinds because the agreement attempted to strike a compromise between developed and developing nations. In order to create a more harmonized international IPRs system, particularly for patents, TRIPS attempts to balance the needs of all its Members.⁴⁴ However, this effort left developing countries conceding more than they received. The cost and side effects of the agreement caused developing countries to be confronted with rising healthcare costs and problem

review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and

(f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

⁴⁰ See TRIPS Preamble, WORLD TRADE ORGANIZATION,

https://www.wto.org/english/docs_e/legal_e/27-trips_02_e.htm

⁴¹ See The Dunkel Draft, From the GATT Secretariat (Inst. for Int'l Legal Info. ed., 1992).

⁴² *Id.*

⁴³ Daniel J. Gervais, *The Trips Agreement: Drafting History and Analysis* 117 (2003).

⁴⁴ Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on The TRIPS Agreement* 23 (1998).

regarding access to medicine.⁴⁵

Prior to TRIPS, developing countries had little incentive to develop rigorous IPRs. In fact, “low standards of patent protection in countries such as India and Brazil, for example, facilitated the development of industries, particularly in the pharmaceutical field.”⁴⁶ An argument presented by parties opposed to creating strong IPRs protection in developing countries is that developing countries need as much access to Western technology as possible to maximize development.⁴⁷ Another argument is that stronger IPRs would force developing countries to pay for the use of intellectual property, which is often owned by individuals and corporations in developed nations, and hamper economic development.⁴⁸

TRIPS’ effect on developing countries varied, partially due to whether those countries had an already established domestic IPRs regime.⁴⁹ Some countries were part of the Paris or the Berne Convention prior to becoming WTO members; therefore, had some form of IPRs protection system, and others had little to no structure.⁵⁰ Regardless, by becoming parties to the WTO, all of these nations committed themselves to high levels of domestic reforms. Because a country’s technological and economic development plays a substantial role in implementing TRIPS minimum standards, another consideration was needed to alleviate the extensive burden developing countries sustained.

In 2001, WTO held the Fourth Ministerial Conference in Doha, Qatar. The Ministerial Conference produced a separate Declaration on TRIPS and Public Health.⁵¹ The key issues covered regarding TRIPS Agreement included technology transfer provisions, compulsory licensing, and extensions for transition periods.⁵² Furthermore, a group of developing countries submitted a proposal during the special session of the TRIPS Council in 2001.⁵³ The proposal notably called for re-balancing of right and

⁴⁵ *Id.*

⁴⁶ Tara Kalagher Giunta & Lily H. Shang, *Ownership of Information in a Global Economy*, 27 Geo. Wash. J. Int’l L. & Econ. 327, 330 (1993–1994).

⁴⁷ Danielle Tully, *Prospects for Progress: The TRIPS Agreement and Developing Countries After the Doha Conference* (2003).

⁴⁸ Giunta & Shang, *supra* note 45, at 332.

⁴⁹ Data in the Annex to Braga, at A9-A11, (listing Membership in GATT and in Major WIPO conventions as of April 5, 1994), and from *Members and Observers*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (containing the date of membership for each member since 2016).

⁵⁰ *Id.*

⁵¹ World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN (01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha].

⁵² See Tully, *supra* note 46, at 139.

⁵³ See Council for Trade-Related Aspects of Intellectual Property Rights General Council: Proposal by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and

obligations in light of public interest. It included “allowances for compulsory licensing without prior attempts to obtain authorization from the rights holder in cases of national emergency or extreme urgency”.⁵⁴ The proposal further called for WTO members “to refrain from threatening or imposing sanctions on developing countries and LDCs when they act within the TRIPS Agreement to promote and protect public health”.⁵⁵

Paragraph 4 of the Doha Declaration clarified on these concerns, stating:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.⁵⁶

This text was a great step forward in fulfilling the priorities for both developed and developing countries. It asserted the existing legal obligations while highlighting the importance of public health over private interest.⁵⁷ Doha clarified that “governments are not only entitled to but have a duty to pursue the necessary public policy health safeguards – so called TRIPS flexibilities necessary to protect public health and promote access to affordable medicines.”⁵⁸

C. Local Working

What is Local Working:

The term ‘local working’ generally refers to the “commercial working of a patent in a country.”⁵⁹ It refers to the condition imposed by governments to have a patented product used or produced in the patent granting country.⁶⁰ It is stated that “this

Venezuela, IP/C/W/312 (Oct. 4, 2001), *available at* https://www.wto.org/english/tratop_e/trips_e/mindecdraft_w312_e.htm [hereinafter Developing Country Proposal].

⁵⁴ Tully, *supra* note 46, at 140 (citing Developing Country Proposal at paras. 4, 10-13).

⁵⁵ *Id.*

⁵⁶ World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN (01)/DEC/2, 41 I.L.M. 755 (2002).

⁵⁷ J. Michael Finger, *The Doha Agenda and Development: A View from the Uruguay Round 19*, (Asian Development Bank, ERD Working Paper Series No. 21, 2002).

⁵⁸ Burcu Kilic, *Defending the Spirit of the DOHA Declaration in Free Trade Agreements: Trans-Pacific Partnership and Access to Affordable Medicines*, 12 Loy. L. Rev. 23, 32 (2014).

⁵⁹ Michael Halewood, *Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law*, 35 Osgoode Hall L. Rev. 245, 268 (1997).

⁶⁰ *Id.* at 246.

condition has the effect of forcing foreign patentees to situate production facilities within the patent granting country.”⁶¹ In the context of compulsory licensing, ‘local working’ refers to the affirmative obligations of patent holders to transfer technology to the country which grants the patent.⁶² While some interpret this to mean local manufacturing, others would allow for importation to satisfy such requirements. In order to import a patented product, “the country in need may apply the international exhaustion principle and allow parallel imports or grant a compulsory license either to import or to manufacture the protected product.”⁶³ These requirements have long existed, along with disclosure requirements, as foundations to the patent system which prevent foreign patentees from abusing intellectual property rights.⁶⁴

The Origins of Local Working Requirement:

Local working of patents has been a long standing right afforded to countries who grant foreign patents.⁶⁵ During the middle ages, England issued patent letters by the Crown to encourage tradesmen and industrialist to move into the country and help develop local economy.⁶⁶ One of the early statutes, The Venetian statute, “was framed in 1337 for the protection of the new industry, was also aimed at industrial development”.⁶⁷ Moreover, it is stated that,

The first monopoly privilege, granted by the Crown to a foreigner Henry Smyth in the form of Letters Patent for the production of Normandy glass, was on the condition of (a) bringing the foreign trade of manufacturing Normandy glass to England, (b) benefiting the realm by lowering the price and (c) training Englishmen in its production.⁶⁸

The Venetian statute asserted that monopolies were against ancient and fundamental laws and patent rights were only granted due to their public benefit.⁶⁹ Local working requirements were always believed to be beneficial “for transfer of technology and

⁶¹ *Id.*

⁶² EDITH T. PENROSE, *THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM* 137 (1951).

⁶³ *Id.* (“Some national laws require, however, the compulsory licensee to locally produce the invention. Unless amended, such legislation can make illusory a solution under paragraph 6 based on either Article 31 (f) or Article 30, since in both cases the assumption is that the compulsory licensee is able to import in order to execute his licence.”).

⁶⁴ *Id.* at 3 (referring to ‘working a patent’ as an “unfortunate piece of technical jargon”).

⁶⁵ For an extensive look into the history of compulsory working in early European patent law see *id.* at 137-167.

⁶⁶ G B Reddy, *Local Working of Patents – Law and Implementation in India*, 18 J. Intell. Prop. Rts., 1, 15-16 (2013).

⁶⁷ *Id.* at 16

⁶⁸ *Id.*

⁶⁹ *Id.*

economic upliftment of the state.”⁷⁰ Therefore, “it was a primary and fundamental obligation on patentees to produce the patented articles within the territory and it always remained the precondition for grant of patents. However, failure to work has always been considered a *prima facie* ‘abuse’ of the patent privilege.”⁷¹ The main objective for having local working in the early history of the patent system remains true today, and that is to encourage innovation and transfer of knowledge to states which offer protection to such patents.⁷²

Local Working Under Paris Convention:

The purpose of local working requirements as stated in the Paris Convention were to ensure that the patent is exploited in the country where it is protected, and to prevent against the “abuse of the monopoly” by patent owners.⁷³ The last revision to the Paris Convention under Article 5(A)(2)⁷⁴ maintains that “each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.”⁷⁵ The language in Article

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² Penrose, *supra* note 63.

⁷³ *Id.* at 78.

⁷⁴ TRIPS, *supra* note 1, at art. 5. Article 5, Section A of the Paris Convention reads,

A(1) Importation by the patentee (b) into the country where the patent has been granted of articles manufactured (c) in any of the countries of the Union (d) shall not entail forfeiture of the patent (e).

(2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses (f) to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent (g), for example, failure to work (h).

(3) Forfeiture of the patent (i) shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses (j). No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license (k).

(4) A compulsory license may not be applied for on the ground of failure to work or insufficient working (l) before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last (m); it shall be refused if the patentee justifies his inaction by legitimate reasons (n). Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license (o); TRIPS, *supra* note 1, at art. 2.

TRIPS art.2 : “In respect of Parts II, III and IV of this Agreement, Members shall *comply with Article 1 through 12*, and Article 19, of the Paris Convention (1967).” (*Emphasis added by author*).

“Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.”;

See Martin J. Adelman, Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 Vand. J. Transnat’l L. 507, 517 (1996) (noting “that Article 27 precludes the claim that satisfying the market demand through imports can be used as a basis for compulsory licensing where satisfying it in the same way through domestic manufacture would not be”).

⁷⁵ Paris Convention, *supra* note 18, at art. 5(A)(2) (

5(A)(2) thus can be interpreted as prima facie evidence that under international law, and the Paris Convention, failure to work a patent is considered an abuse of the patent monopoly.⁷⁶ Although this language was not present in the original text of the Paris Convention, it was later added during the Conference of the Hague and allowed members to include “regulation of legislation measures intended to prevent the abuses...of which failure to work was cited as an example.”⁷⁷ The convention also allows member states to freely define “failure to work.”⁷⁸ This could include the refusal to grant licenses on reasonable terms, insufficient supply of the national market, or excessive prices.

In the early days, failure to work a patent within countries that had local working provisions meant the country had the right to completely revoke such patent.⁷⁹ Complete revocation of patents for failure to work was later rejected by the Paris Convention.⁸⁰ Prior to the usage of Paris Article 5, less extreme remedies, such as compulsory licensing, had not yet been introduced. Therefore, patentees could have forfeiture of right even if a country had provisions that stipulated that the patentee was not allowed to import any of the patented material.⁸¹ Article 5(1) “was designed to end what was widely felt to be an abuse of the working requirement—forfeiture on the basis of some importation.”⁸²

Current local working provisions are consistent with the goal of technology transfer, and are considered affirmative obligations on patent holders.⁸³ These affirmative obligations were guided by the notion that patents were expected to serve

“Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, *failure to work*.” (*Emphasis added by author*)).

⁷⁶ *Id.*

⁷⁷ G.H.C. Bodenhause, *Guide to the Application of the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967*, 68 (1969).

⁷⁸ *Id.* at 71 (explaining working requirements:

“The member States are also free to define what they understand by ‘failure to work.’ Normally, working a patent will be understood to mean working it industrially, namely, by manufacture of the patented product, or industrial application of a patented process. Thus, importation or sale of the patented article, or of the article manufactured by a patented process, will not normally be regarded as ‘working’ the patent.

The member States are equally free to decide whether legislative measures will be taken already in the case of failure to work a patent in the country concerned, or only if such failure to work occurs in a larger territory comprising one or more other countries.”).

⁷⁹ *See id.* at 67-69.

⁸⁰ *See id.* at 68, 73.

⁸¹ *See* Halewood, *supra* note 58, at 251.

⁸² *Id.* at 252.

⁸³ Paul Champ & Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the US-Brazil Patent Dispute*, 27 Yale J. Int’l L. 365, 370 (2002).

domestic industry.⁸⁴

The principle of “national treatment”⁸⁵ to treat foreign products equal to domestic ones does not preclude local working requirements. This is supported by the fact that even when the Paris Convention introduced national treatment, many States, party to the convention, maintained provisions that allowed for working requirements in domestic legislation.⁸⁶ The rights of members under the Paris Convention to enact local working provisions in their domestic legislation did not end with the Paris Convention, as this treaty was later incorporated into the TRIPS agreement.⁸⁷

Local Working and the TRIPS Agreement:

Local working provisions are consistent with international laws, the Vienna Convention rules on treaty interpretation,⁸⁸ as well as the TRIPS agreement. The inclusion of Article 5(A) of the Paris Convention into TRIPS Article 1⁸⁹ and 2⁹⁰ asserts

⁸⁴ See Marketa Trimble, *Patent Working Requirements: Historical and Comparative Perspectives*, 6 U.C. Irvine L. Rev. 483, 487 (2016).

⁸⁵ National treatment as defined by the WTO is the principle of giving others the same treatment as one's own nationals. GATT Article 3 requires imports be treated no less favorably than the same or similar domestically-produced goods once they have passed customs. GATS Article 17 and TRIPS Article 3 also deal with national treatment for services and intellectual property protection. Glossary Term. *National Treatment*, WORLD TRADE ORGANIZATION,, https://www.wto.org/english/thewto_e/glossary_e/national_treatment_e.htm.

⁸⁶ See Trimble, *supra* note 83, at 487.

⁸⁷ Champ & Attaran, *supra* note 82, at 372.

⁸⁸ See Vienna Convention, *supra* note 15, at art. 30; see id. art. 31; see id. art. 32; see id. art. 33.

⁸⁹ TRIPS, *supra* note 1, at art. 1. The full text of TRIPS Article 1 reads,
Nature and Scope of Obligations

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

2. For the purposes of this Agreement, the term “intellectual property” refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.

3. Members shall accord the treatment provided for in this Agreement to the nationals of other Members. In respect of the relevant intellectual property right, the nationals of other Members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits, were all Members of the WTO members of those conventions. Any Member availing itself of the possibilities provided in paragraph 3 of Article 5 or paragraph 2 of Article 6 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for Trade-Related Aspects of Intellectual Property Rights (the “Council for TRIPS”).

⁹⁰ TRIPS, *supra* note 1, at art. 2. Article 2 of TRIPS reads,
Intellectual Property Conventions

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).

local working requirements as a means of balancing patent protections with developing domestic economies

It is clear that TRIPS Article 1 and 2 impose obligations from the Paris Convention on WTO members. However, an argument still being debated is whether issuing a compulsory license on the basis of local working requirement is still permitted under TRIPS.⁹¹ In support of this argument, it is presented that Article 27 is “absolute” over the exceptions allowed by Articles 30⁹² and 31 of the TRIPS agreement.⁹³

This argument was brought up in the Canada – Patent Protection of Pharmaceutical Products case. In this case, European Communities (EC) requested “consultations with Canada in respect of the alleged lack of protection of inventions by Canada in the area of pharmaceuticals under the relevant provisions of the Canadian implementing legislation, in particular, the Patent Act.”⁹⁴ The EC alleged that Canada’s Patent Act, Section 55.2(1)⁹⁵ “is not compatible with its obligations under the TRIPS Agreement, because it does not provide for the full protection of patented pharmaceutical inventions for the entire duration of the term of protection envisaged by Articles 27.1, 28 and 33 of the TRIPS Agreement.”⁹⁶ With respect to TRIPS Article 27, the EC alleged that, while Canada asserted that the contested provisions could in the future also apply to other fields of technology, the fact remained that ever since their enactment the provisions

2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

⁹¹ See Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 Vand. J. Transnat’l L. 507, 517 (1996) (noting “that Article 27 precludes the claim that satisfying the market demand through imports can be used as a basis for compulsory licensing where satisfying it in the same way through domestic manufacture would not be”).

⁹² TRIPS art. 30.

⁹³ Canada — Patent Protection of Pharmaceutical Products — Complaint By The European Communities and their member States, , WT/DS114/R, 17 March 2000, at 31 (“European Communities and their member states did not seek to read article 27.1 in its context and in light of the TRIPS objective, but instead, asserted that Article 27.1 was absolute in nature, such that ‘violations’ of its provisions could not be justified...”) [hereafter EC-Canada].

⁹⁴ Complaint by the European Communities and their member States, World Trade Organization (Feb. 24, 2010), https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm.

⁹⁵ *Id.* The specific language of the exceptions in the Canadian Patent Law were the following:

The Regulatory Review Exception, Section 55.2(1):

“It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, or construction, use or sale of any product.”

The Stockpiling Exception, Section 55.2(2):

“It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for manufacture and storage of articles intended for sale and after the date on which the term of the patent expires.”

⁹⁶ Complaint by the European Communities and their member States, *supra* note 93.

had only applied to patents for pharmaceuticals. There could be no doubt that this situation constituted a violation of the non-discrimination obligation as to fields of technology contained in Article 27.1 of the TRIPS Agreement, by treating owners of patents in the area of pharmaceuticals less favourably than owners of patents in all other product areas. The drafting history of Section 55.2(1) made it utterly clear that the legislator's intent had been to limit the effects of the provisions to pharmaceutical products. Elaborating on this, in response to a question from the Panel, the European Communities and their member States expressed the view that, while they considered Section 55.2(1) of the Canadian Patent Act to constitute a *de jure* violation of Article 27.1 of the TRIPS Agreement, Section 55.2(1) would also violate Article 27.1 if one were to consider that it only constituted *de facto* discrimination.⁹⁷

Canada's counter argument was that Article 27.1 does not apply "across the board" in a manner contended for by the EC. Canada further argued that if the EC interpretation did apply,⁹⁸ Article 30 of the Agreement would be reduced to inutility, contrary to the first principles of treaty interpretation.⁹⁹ Those principles recognized that different treaty provisions could interact in different ways. Hence, it was appropriate to conclude that the "patent rights" referred to in Article 27.1 were the rights enumerated in Article 28.1 subject to limited exceptions imposed under Article 30, but not subject to "other use" under Article 31. The EC's opinion that the non-discrimination requirement of Article 27.1 of the TRIPS Agreement applied "across the board," and did not allow any scope for the recognition of limited exceptions under Article 30, was not shared by any of the third parties to the dispute other than Switzerland.

The EC's proposed interpretation of Article 27.1 would render Article 30 of the Agreement nugatory, since no exception could be both broad enough to satisfy the [anti-discrimination] requirement of Article 27.1 and, at the same time, narrow enough to meet the test of "limited exception" in Article 30. Similarly, the "absolute" construction advocated by Switzerland as a third party in the dispute would reduce Article 30 to meaninglessness. While Switzerland suggested that Canada's interpretation could only arise if the words "Subject to the provisions of this Section (or Article 30) [...]" were added at the opening of the second sentence of Article 27.1, such additional language would mean that Article 30 could be used to deny patent availability. An exception of this nature would hardly be "limited," and would not be consistent with the other requirements of Article 30.¹⁰⁰

The report of the panel for this case stated, "the acknowledged fact that the Article 31 exception for compulsory licenses and government use is understood to be subject to

⁹⁷ EC-Canada at 47.

⁹⁸ *Id.* at 170.

⁹⁹ *Id.* at 66-67.

¹⁰⁰ *Id.*

the non-discrimination rule of Article 27.1.”¹⁰¹ A counter argument to this is that the panel is “acknowledged” approach to Article 27 did not follow proper rules of interpretation.¹⁰² Proper application of the Vienna rules of treaty interpretation to the issue of Article 31’s relation to Article 27 will follow under Part II of this article.

II. IS TRIPS A SUBSEQUENT AGREEMENT TO THE PARIS CONVENTION?

A. *New Assault on Local Working*

In the past decades since the implementation of the TRIPS agreement, advocates for patent right holders have been making the push to strengthen patent protection.¹⁰³ An argument for this position is that providing the maximum protection for patents is best for the social interest and welfare of developing communities.¹⁰⁴ While the effort to limit TRIPS’ flexibilities of developing countries permitted under TRIPS is not an entirely new issue,¹⁰⁵ what is of concern is the threat of doing away with such rights within the context of Free Trade Agreement (FTA) negotiations currently taking place.¹⁰⁶

Developed countries, such as the United States, challenged the local working grounds for compulsory licensing in many developing nations. In the *United States v. Brazil* dispute, United States challenged the local working aspects of the Brazilian Industrial Property Law by claiming it violated Article 27(1) of TRIPS, which prohibits discrimination as to “whether products are imported or locally produced.”¹⁰⁷ This was a case that came close to resolving the issue of whether the local working requirements are legal under TRIPS. However, the case settled before final decision could be issued and the legality of local working requirements has remained unanswered.

¹⁰¹ *Id.* at 170.

¹⁰² Champ & Attaran, *supra* note 82, at 388.

¹⁰³ See Halewood, *supra* note 58, at 246 (discussing “compulsory licensing” and “local working” as methods countries use to strengthen patent protection).

¹⁰⁴ *Id.*

¹⁰⁵ Yu, *supra* note 6, at. 980 (stating that less-developed countries are “frustrated by the current ongoing demands by developed countries for protections that are in excess of what they promised during the TRIPS negotiations”).

¹⁰⁶ Letter from Karel De Gucht, European Commissioner for Trade, to Tido von Schoen-Angerer, Exec. Director, Campaign for Access to Essential Medicines: Medecins Sans Frontieres International (May 25, 2010) (regarding concerns about the possible effects of the FTA negotiations with India on access to medicines), https://msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_letter_ECTradeCommisioner_Gucht_ENG_2010.pdf.

¹⁰⁷ TRIPS art. 27(1); *see also* Brazil - Measures Affecting Patent Protection-Notification of Mutually Agreed Solution, WTO Doc. WT/DS199/4/G/L/454/IP/D/23/Add.1(adopted July 19, 2001).

Currently, India is involved in negotiations for a new FTA with a group of European countries known as the European Free Trade Association (EFTA).¹⁰⁸ In a leaked document available at Knowledge Ecology International, under subsection (a) entitled “patent protection,” the Swiss side requests: “it will be essential for parties to confirm that the import of patented product is accepted as working (i.e. use) of the patent.”¹⁰⁹ The broad working for the fulfillment of working would be detrimental and would undermine the working requirements purpose of protection against abuses of intellectual property rights by patent holders.¹¹⁰

B. WTO’s Stance on Local Working

Prior decisions of WTO cases do not signal a definitive stance against local working requirements. Neither panel decisions nor Appellate Body reports are technically legally binding on future panels or the Appellate Body. Although, as time passes, this becomes less of the position in reality as there is now a coherent body of WTO procedural and substantive law.¹¹¹ While a WTO panel has yet to take up the issue of local working requirements,¹¹² it has however, taken on the issue of the relationships between Article 27 and Articles 30 and 31 of the TRIPS agreements in the EC-Canada case as mentioned above.¹¹³

The latest specific WTO document on the topic of intellectual property as it relates to access to medicines is the Doha Declaration. Since Doha, there has been a shift in the understanding of IP rights, and in the recognition that human rights and IP are becoming more intertwined in recent years than perhaps it was initially imagined.¹¹⁴ An example of the recognition of the importance of human rights within IP was the UN Sub-Commission on the Promotion and Protection of Human Rights’ recommendation concerning “the primacy of human rights obligations over economic policies and agreements.”¹¹⁵ This recommendation is further evidence of the responsibilities a

¹⁰⁸ The group of countries engaged in negotiations with India are Switzerland, Norway, Iceland, and Liechtenstein. India-EFTA TEPA, Chapter on the Protection of Intellectual Property - Note by Switzerland (Mar. 15, 2017),

<https://www.keionline.org/wp-content/uploads/2017/10/Swiss-India-EFTA-TEPA-IP-Chapter-15March2017.pdf>.

¹⁰⁹ *Id.*

¹¹⁰ Paris Convention art. 5(A)(2).

¹¹¹ Donald McRae, *What is the Future of WTO Dispute Settlement?* 7 J. Int’l. Econ.L. 1, 3 (2004).

¹¹² Peter Meyer, *Brazil: Background and U.S. Relations*, Congressional Research Service RL33456 (2016).

¹¹³ See EC-Canada.

¹¹⁴ See Yu, *supra* note 6, at 1042 (explaining that one type of obligation is not “subordinate” to the other, and instead careful analysis of both IP policy and human right policy should be done to reach appropriate balance).

¹¹⁵ *Id.* at 1036.

government has in protecting its citizens during a public health crisis through flexibilities such as compulsory licensing.

C. Legal Status

According to the Vienna Convention, a treaty should be interpreted in good faith using the ordinary meaning of its terms in context and in light of the treaty's object and purpose.¹¹⁶ When interpreting international treaties, "text, context, object and purpose, and good faith are used 'as one holistic rule of interpretation rather than a sequence of separate tests to be applied in a hierarchical order.'"¹¹⁷ Article 3 (2) of the WTO's DSU incorporates this rule by requiring the dispute settlement panels to clarify WTO provisions "in accordance with customary rules of interpretation of public international law."¹¹⁸ Only where application of this rule results in ambiguity can supplementary means of interpretation be used.¹¹⁹ Subsequent agreements and practice are recognized supplementary means of treaty interpretation under customary international law.¹²⁰

A debate over a potential conflict between the obligation under Article 27(1) of TRIPS and the right granted by Article 5(A)(2) of the Paris Convention has emerged over the years. The argument is whether TRIPS is a subsequent agreement to Paris, rather than TRIPS being a stand-alone agreement with provisions of the Paris Convention incorporated in it. To recap, the relevant treaties in question are as follows:

Article 27(1) of TRIPS: Patents shall be available and patent rights enjoyable

¹¹⁶ Vienna Convention art. 31, § 1; *see also*, Helge Elisabeth Zeitler; 'Good Faith' in the WTO Jurisprudence – Necessary Balancing Element or an Open Door to Judicial Activism? 8 J.Int'l Econ L., 721, 722 (2005) ("In WTO law, good faith is a term that plays an important role on different levels and under many different names. The concept is mentioned explicitly only in the TRIPS Agreement and in the Understanding for the Settlement of Disputes (DSU). However, through the link in Article 3.2 of the DSU to the interpretation principles of customary international law and thereby to Article 31 of the Vienna Convention on the Law of the Treaties, good faith has also gained some importance in the understanding of other agreements. Finally, another provision of the Vienna Convention, Article 26 ('Every treaty in force is binding upon the parties to it and must be performed by them in good faith', plays some important role, as well.").

¹¹⁷ Panel Report, United States - Sections 301-310 of the Trade Act of 1974, WTO Doc. WT/DS152/R ¶ 7.22 (adopted Dec. 22, 1999).

¹¹⁸ DSU, Dispute Settlement Rules: Understanding on Rules and Procedures Governing the Settlement of Disputes, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401, 33 I.L.M. 1226 (1994) [hereinafter DSU]. ("The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements.").

¹¹⁹ Oliver Dörr & Kirsten Schmalenbach, Supplementary Means of Interpretation, in Vienna Convention on the Law of Treaties, a Commentary, Dörr Oliver & Kirsten Schmalenbach, eds., 2012).

¹²⁰ *Id.*

without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.¹²¹

Article 5(A)(2) of the Paris Convention: Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.¹²²

Article 2(2) of TRIPS: Nothing in Parts I to IV shall derogate from existing obligations that members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention, and the Treaty on Intellectual Property in Respect of Integrated Circuits.¹²³

As mentioned previously, WTO's DSU and the Appellate Body have interpreted the TRIPS Agreement by referring to the customary rules of treaty interpretation, notably using Article 31 and 32 of the Vienna Convention. Article 32¹²⁴ deals with "with the use of supplementary means in the process of treaty interpretation and with the relationship of that use to the general rule of interpretation laid down in Art 31."¹²⁵ It is stated that when "the examination of 'preparatory work' for the elaboration of the TRIPS Agreement was needed, the text, guidelines and model laws relating to the relevant provisions of the Paris or Berne Conventions were often referred to as 'contextual guidance' or 'contextual support.'"¹²⁶ In support of this, the Appellate Body in US-Section 211 Appropriation Act stated that "Article 6 *quinquies* of the Paris Convention offered 'contextual support.'"¹²⁷

In the US — Section 211 Appropriations Act dispute, the European Communities (EC) alleged that "section 211 US Omnibus Appropriations Act was not in conformity with the US' obligations under the TRIPS Agreement, notably its Article 2 in conjunction with the Paris Convention, Article 3, Article 4, Articles 15 to 21, Article 41, Article 42 and Article 62."¹²⁸ The EC argued that, Section 211(b)¹²⁹ violates the US

¹²¹ TRIPS art. 27 (1).

¹²² Paris art. 5 (A) (2).

¹²³ TRIPS art. 2(2).

¹²⁴ The full text of Vienna Convention art. 32, Supplementary means of interpretation recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31:

(a) leaves the meaning ambiguous or obscure; or

(b) leads to a result which is manifestly absurd or unreasonable.

¹²⁵ Dörr Ch. 32 at 1.

¹²⁶ *Id.*

¹²⁷ *Id.* citing to United States — Section 211 Omnibus Appropriations Act of 1998, WT/DS176/11/Add.156 | 15 January 2016.

¹²⁸ United States — Section 211 Omnibus Appropriations Act of 1998, WT/DS176/11/Add.156 | 15 January 2016.

¹²⁹ Section 211 (b) of the Omnibus Appropriation Act reads,

(b) No U.S. court shall recognize, enforce or otherwise validate any assertion of treaty rights by a

obligations under Article 2.1 of the TRIPS Agreement together with Articles 6bis (1)¹³⁰ and 8¹³¹ of the Paris Convention (1967) as set out under its arguments concerning Section 211(a)(2). Section 211(b) also violates the national treatment obligations of the United States as contained in Article 3.1¹³² of the TRIPS Agreement and Article 2.1 of the TRIPS Agreement together with Article 2(1) of the Paris Convention (1967) for the reasons the European Communities points out in its arguments concerning Section 211(a)(2). Finally, the European Communities claims that Section 211(b) is

designated national or its successor-in-interest under sections 44 (b) or (e) of the Trademark Act of 1946 (15 U.S.C. 1126 (b) or (e)) for a mark, trade name, or commercial name that is the same as or substantially similar to a mark, trade name, or commercial name that was used in connection with a business or assets that were confiscated unless the original owner of such mark, trade name, or commercial name, or the bona fide successor-in-interest has expressly consented.

¹³⁰ Article 6bis of Paris Convention reads,

Marks: *Well-Known Marks*

(1) The countries of the Union undertake, ex officio if their legislation so permits, or at the request of an interested party, to refuse or to cancel the registration, and to prohibit the use, of a trademark which constitutes a reproduction, an imitation, or a translation, liable to create confusion, of a mark considered by the competent authority of the country of registration or use to be well known in that country as being already the mark of a person entitled to the benefits of this Convention and used for identical or similar goods. These provisions shall also apply when the essential part of the mark constitutes a reproduction of any such well-known mark or an imitation liable to create confusion therewith.

(2) A period of at least five years from the date of registration shall be allowed for requesting the cancellation of such a mark. The countries of the Union may provide for a period within which the prohibition of use must be requested.

(3) No time limit shall be fixed for requesting the cancellation or the prohibition of the use of marks registered or used in bad faith.

See also USPTO's *Well-known Marks* explaining (Article 6bis of the Paris Convention for the Protection of Industrial Property (1967) requires member countries to afford certain protections to well-known marks, regardless of whether they are registered. Specifically, member countries must refuse or cancel the registration, and prohibit the use, of a well-known mark when applied for or used by an unauthorized party for identical or similar goods, when its use or registration would likely cause confusion. Article 16.2 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) extends Paris Convention Article 6bis to services and provides that members shall take into account that a mark is well-known to a relevant sector of the public (not the entire country) as well as promotion of the mark (not just use). Article 16.3 of TRIPS extends Art. 6bis protection to well-known marks when used on unrelated goods or services in cases where the well-known mark is registered, if such use indicates a connection to the owner and the well-known mark owner would likely be damaged.)

¹³¹ Article 8 of the Paris Convention reads, Trade Names. A trade name shall be protected in all the countries of the Union without the obligation of filing or registration, whether or not it forms part of a trademark.

¹³² TRIPS Article 3(1) reads, National Treatment. 1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.

incompatible with the United States' obligations under Article 4¹³³ of the TRIPS Agreement for the reasons it mentioned in its arguments concerning Section 211(a)(2).¹³⁴

In resolving the dispute, the DSU panel requested a letter to the International Bureau of WIPO to provide the panel with "with factual information, in particular the negotiating history and subsequent developments, concerning the provisions of the Paris Convention (1967) relevant to the dispute, including Articles 2(1), 6, 6*bis*, 6 *quinquies* and 8 of the Paris Convention (1967)."¹³⁵ At the end, the panel held that "Section 211(a)(2) is not inconsistent with Article 6*bis* of the Paris Convention (1967) as incorporated into the TRIPS Agreement."¹³⁶ The reasonings behind the panel's decisions include that in Article 2.1 of TRIPS, the second subclause of Article 2.1 obliges Members to comply with the provisions of the Paris Convention (1967) which are identified in that [Article 2.1 of TRIPS] provision. However, the second subclause is conditioned by the first subclause: Members shall comply with the obligations "[i]n respect of Parts II, III, and IV of this Agreement." As the ordinary meaning of the term "in respect of" is in "relation [to], connection [with], reference [to]" and it refers to Parts II, III and IV explicitly, we consider that Members have to comply with Articles 1 through 12 and 19 of the Paris Convention (1967) "in respect" of what is covered by those parts of the TRIPS Agreement identified therein, namely copyright and related rights; trademarks; geographical indications; industrial designs; patents; layout-designs (topographies) of integrated circuits; and protection of undisclosed information.¹³⁷

The Panel also held that the phrase "intellectual property" in Article 1.2 designated all categories of IP. The report stated that, we [the panel] interpret the terms "intellectual property" and "intellectual property rights" with reference to the definition

¹³³ TRIPS Article 4 reads, Most-Favored-Nation Treatment. With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member: (a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property; (b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country; (c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement; (d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.

¹³⁴ United States — Section 211 Omnibus Appropriations Act of 1998, WT/DS176/11/Add.156 | 15 January 2016 at 4.148.

¹³⁵ *Id.* at 8.13.

¹³⁶ *Id.* at 8.121.

¹³⁷ *Id.* at 8.30.

of “intellectual property” in Article 1.2 of the TRIPS Agreement. The textual reading of Article 1.2 is that it establishes an inclusive definition and this is confirmed by the words “all categories;” the word “all” indicates that this is an exhaustive list. Thus, for example, the national and most-favoured-nation treatment obligations contained in Articles 3 and 4 of the TRIPS Agreement that refer to the “protection of intellectual property” would be interpreted to mean the categories covered by Article 1.2 of the TRIPS Agreement. We consider the correct interpretation to be that there are no obligations under those Articles in relation to categories of intellectual property not set forth in Article 1.2, e.g., trade names, consistent with Article 31 of the Vienna Convention.¹³⁸

This body of law establishes that when interpreting treaties in light of the Vienna Convention, Article 27.1 of TRIPS, and Article 5 of Paris in this case, the WTO will rely on the interpretation that Paris is incorporated within TRIPS. Thus, TRIPS is not a subsequent agreement to Paris.

III. LOCAL WORKING UNDER TRIPS

While some believe that local working requirements could in fact be economically unfavorable, the rationale followed by this article, and others in the past has been¹³⁹ that working requirements should not be evaluated alone, but in context with a State’s patent system.^{140,141} If done so properly, an analysis of the legal text on the topic and subsequent practice by States would show that under the current international system of intellectual property, local working requirements are still an option available to States when determining grounds for compulsory licenses. A right which should not be extinguished by accepting mere importation to fulfill its mandate.

A. *Non-Discriminatory Local Working Requirements*

Under TRIPS Article 27.1, members are not to discriminate with respect to the enjoyment of patents rights on the basis of the (a) place of invention, (b) field of technology and (c) whether products are imported or locally produced.¹⁴² The legality of whether imported or locally produced products serving as the basis for issuing a compulsory license has yet to be answered.

¹³⁸ *Id.* at 8.26.

¹³⁹ See Trimble, *supra* note 83, at 487 (arguing the importance of local working requirements).

¹⁴⁰ Penrose at 143 (noting that it is not economic for countries to produce at home all products desired by local market but to import many goods which can be more cheaply produced in other countries).

¹⁴¹ See Trimble, *supra* note 83, at 487 (arguing the importance of local working requirements).

¹⁴² TRIPS art. 27.1.

Discrimination in the EC – Canada Dispute:

The most relevant case at hand which dealt with the issue of non-discrimination under Article 27.1 was the Canada Pharmaceutical case. Hence, the following analysis of Article 27 will largely be surrounding the interpretation of the case.

Article 27.1 of TRIPS states, *inter alia*, that “patents shall be available for any invention....provided that they are new, involve an inventive step and are capable of industrial application.”¹⁴³ Primarily, TRIPS negotiators proposed Article 27.1 to eliminate discrimination practiced against pharmaceuticals and certain other products.¹⁴⁴ The discriminatory behavior was meant to deter denial of patentability for these products, or *automatic* compulsory licenses permitting others to manufacture such products for a fee.¹⁴⁵

The discrimination argument in the EC – Canada case was that “the EC claimed that Section 55.2(1) of the Canada Patent Act is in conflict with the obligations under Article 27.1 of the TRIPS Agreement.”¹⁴⁶ Below are the contentions presented in the application of Article 27.1.

The EC argued that the anti-discrimination rule stated in the italicized language in the text of Article 27.1 above not only requires that the core patent rights made available under Article 28 be non-discriminatory, but also requires that any exceptions to those basic rights made under Articles 30 and 31 must be non-discriminatory as well. Thus, the EC concluded, Article 27.1 requires that the exception made by Section 55.2(1) must be non-discriminatory. The EC contended that Section 55.2(1) does not comply with the obligations of Article 27.1, because it is limited, both *de jure* and *de facto*, to pharmaceutical products alone, and thus discriminates by field of technology.¹⁴⁷

Canada took the position that Article 27.1’s reference to “patent rights” that must be enjoyable without discrimination as to field of technology refers to the basic rights

¹⁴³ *Id.* The French patent law provides that: “Where the interest of public health demand, patents granted for medicines or for processes for obtaining medicines for products necessary in obtaining such medicines or for processes for manufacturing such products may be subject to ex officio licenses in accordance with Article L. 613-17 in the event of such medicines being made available to the public in insufficient quantity or quality or at (abnormally high prices) by order of the Minister responsible for industrial property at the request of the Minister responsible for health.” (Law No. 92-597 of 1 July, 1992, Article L. 613-16); *See also* Taubman et.al. *A Handbook on the WTO TRIPS Agreement* (2011) (Three substantive conditions are recognized as the basic test of patentability, namely novelty, inventive step and industrial applicability, which were already present in some form in many countries’ laws prior to the TRIPS agreement. In addition to these three tests of patentability, there is one other condition that is considered to be substantive, namely that of disclosure of the invention).

¹⁴⁴ EC-Canada, ¶ 7.90 at 170.

¹⁴⁵ *Id.*

¹⁴⁶ *Id.* ¶ 7.85 at 169.

¹⁴⁷ *Id.* ¶ 7.86 at 169.

enumerated in Article 28.1 subject to any exceptions that might be made under Article 30. In other words, governments may discriminate when making the “limited” exceptions allowed under Article 30, but they may not discriminate as to patent rights as modified by such exceptions.¹⁴⁸

Canada acknowledged that there are certain textual difficulties with this position. It acknowledged that two of the primary purposes of Article 27.1 were to eliminate two types of discrimination that had been practised against pharmaceuticals and certain other products - either a denial of patentability for such products, or, if patents were granted, automatic compulsory licences permitting others to manufacture such products for a fee. *Canada acknowledged that, in order to preclude discrimination as to compulsory licences, the non-discrimination rule of Article 27 was made applicable to Article 31 of the TRIPS Agreement*, which grants a limited exception for compulsory licences under specified conditions. To defend its position, therefore, Canada was required to explain how Article 27.1 could apply to exceptions made under Article 31, but not to exceptions made under its neighbouring exception provision in Article 30. Canada argued that Article 31 was “mandatory” in character while Article 30 was “permissive,” and that this distinction made it appropriate to apply the non-discrimination provision to the former but not the latter.¹⁴⁹

The panel found “the anti-discrimination rule of Article 27.1 does apply to exceptions of the kind authorized by Article 30.”¹⁵⁰ However, European Communities failed to prove that the regulatory review provision discriminated based on the field of technology (e.g. against pharmaceutical products in this case) as described under TRIPS Art. 27.1. The panel saw that countries may treat different fields of patent protection differently if they do for a legitimate purpose. It stated that the ordinary meaning of the word “discriminate” certainly extends beyond the concepts of different treatment; “It is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantage treatment.”¹⁵¹ The panel elaborated that “discrimination may arise from explicitly different treatment, sometimes called ‘*de jure* discrimination’, but it may also arise from ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects, sometimes called ‘*de facto* discrimination’”.¹⁵²

The panel concluded that “Section 55.2(1) of Canada’s Patent Act is not inconsistent with Canada’s obligations under Article 27.1 and Article 28.1 of the TRIPS

¹⁴⁸ *Id.* ¶ 7.88 at 169.

¹⁴⁹ *Id.* ¶ 7.90 at 170.

¹⁵⁰ EC-Canada, para. 7.93 at 171.

¹⁵¹ *Id.* ¶ 7.94 at 171.

¹⁵² *Id.*

Agreement.”¹⁵³ It disagreed with Canada’s interpretation of Article 27.1 of the TRIPS Agreement applied “across the board,” and did not allow any scope for the recognition of limited exceptions under Article 30. As applied to Section 55.2 of the Canadian Patent Act, discrimination by law between technology fields was not in evidence.¹⁵⁴ Additionally, TRIPS did *not* prevent governments from addressing problems that may only exist in “certain product areas.”¹⁵⁵ Governments may still differentiate between patentable technology field for good faith i.e. bona fide reasons.¹⁵⁶ And while the Canadian legislative history focused on the impact of Section 55.2 in the pharmaceutical field, this did not constitute a discriminatory purpose.¹⁵⁷ There was no evidence that in practice the provision did not apply to other products e.g. food, chemicals, cosmetics; an alleged incidental higher impact on patented pharmaceuticals did not rise to the level of discrimination.¹⁵⁸

Reasonable Grounds for Local Working:

Article 31 of TRIPS allows member states to grant compulsory licenses on grounds to be determined by each member country.¹⁵⁹ TRIPS does not specify reasons that justify the issue of compulsory licensing; however, Article 31 makes it clear that compulsory licensing could be issued for national emergencies, other circumstances of extreme urgency, and anti-competitive practices.¹⁶⁰ This provision is further supported by Doha declaration 5(b) and (c).¹⁶¹ Moreover, proper interpretation of TRIPS would

¹⁵³ *Id.* ¶ 8.1 at 174.

¹⁵⁴ *Id.* ¶ 7.99 at 172.

¹⁵⁵ *Id.* ¶ 7.92 at 171-72 (stating “Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than a frustration of purpose. It is quite plausible, as the EC argued, that the TRIPS Agreement would want to require governments to apply exceptions in a nondiscriminatory manner, in order to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers).

¹⁵⁶ *See* EC-Canada, ¶ 7.92 at 171-72.

¹⁵⁷ *Id.* ¶ 7.104 at 173.

¹⁵⁸ *Id.* ¶ 7.102 at 173.

¹⁵⁹ TRIPS, art. 31.

¹⁶⁰ *Id.*

¹⁶¹ World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc.

WT/MIN(01)/DEC/W/2, 41 I.L.M. 746 (2001) (“(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”).

allow compulsory licenses on the grounds of lack of local working, mainly because Article 31, read with Article 6¹⁶² and 8¹⁶³ would prevail over Article 27 (1).¹⁶⁴ Below are some of grounds upon which compulsory licenses could be issued on the basis of lack of local working.

Technology Transfer:

Failure to work is a form of Intellectual Property Rights by patent holders. It can negatively impact growth of industry and transfer of technology in developing countries. This practice runs counter to the intellectual property system's goal to provide society with the long-term benefits that come in exchange for patent protection. In the pharmaceutical sector, this is especially troubling because it may leave developing markets at the mercy of big pharmaceutical corporations' will to choose on how to best serve the market through importation at any measure, without any minimum or reasonably adequate standards in place to satisfy.

International technology transfers and intellectual property rights protection are closely related. On one hand, local productions could impede the development of technology by imitation or reverse engineering. On the other hand, strict patent regulation could delay technology transfer to developing technology. A forward-looking IP regime strives to balance protection of new technology with the need of economic development in the patent granting country.

This principle is further established in the Doha Declaration. The intent of members to promote the transfer of technology from developed to developing countries is asserted in the declaration. Doha states that "the commitment of developed country Members to provide incentive to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2."¹⁶⁵ This goes along with the obligation of patent holders to put their innovation

¹⁶² TRIPS, art. 6.

(Exhaustion- For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.)

¹⁶³ TRIPS, art. 8.

(Principles (1) Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. (2) Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.)

¹⁶⁴ See Champ & Attaran, *supra* note 82, at 370.

¹⁶⁵ Doha, *supra* note 161; Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, 12 WHO Health Economics and Drugs 36, n.106 (June 2002) ("Also note that paragraph 11.2 of the Implementation Decision adopted on 14 November 2001 states the following: 'Reaffirming that the provisions of Article 66.2 of the TRIPS Agreement are mandatory, it is agreed that the TRIPS Council shall put in place a mechanism for ensuring the monitoring and full implementation

into effect in the local industry. There should be recognition that local manufacturing may not always be possible due to a lack of resources and a sufficiently large domestic economy.¹⁶⁶ Nonetheless, there should still be an option for countries to require local manufacturing as a way to facilitate the transfer of technology that the patent system is intended to promote.¹⁶⁷ As mentioned previously, even early statutes on industrial property rights were framed in a way that brought foreign trade to England to benefit the economy by lowering the price of the patented good, as well as training Englishmen in its production.¹⁶⁸

While promotion of technology transfer through local working is clear, some countries have relaxed their approach to local working to allow for importation because it may not always be practicably or economically feasible to manufacture a patent locally.¹⁶⁹ This is a valid point. However, requiring some importation to fulfill local working in all cases would undermine the efforts to promote technology transfer. In instances where it is economically feasible to work the patent domestically, the patent holder would not want to do so. Rather, the patent holder would simply have to import small amounts of its patented product into the country to prevent use of a compulsory license.¹⁷⁰ To prevent such manipulations that disadvantage the patent issuing nation, and to promote national growth, patent issuing countries should have the liberty of issuing compulsory licenses on the ground of lack of local working. Another ground on which local working would be mandated is when ensuring public health safety. This concept is discussed below.

Stricter IPRs create significant costs for patients. Countries forced to adopt strict patent protection for pharmaceuticals are forced to take on substantially higher prices for medicine, which in turn has adverse consequences for the health and well-being of its citizens. For instance, in 2007, Brazil signed a compulsory license that allows the country to make or import a generic version of Efavirenz, a patented anti-HIV drug. Once the compulsory license is issued, the price of Efavirenz dropped down from \$580

of the obligations in question. To this end, developed-country members shall submit prior to the end of 2002 detailed reports on the functioning in practice of the incentives provided to their enterprises for the transfer of technology in pursuance of their commitments under Article 66.2. These submissions shall be subject to a review in the TRIPS Council and information shall be updated by Members annually.' For information on home country measures encouraging transfer of technology, see IP/C/W/132, Add. 1-7").

¹⁶⁶ World Health Organization, *Indian Policies to Promote Local Production of Pharmaceutical Products and Protect Public Health*, at 23 (2017).

¹⁶⁷ *Id.* at 13.

¹⁶⁸ Reddy, *supra* note 67.

¹⁶⁹ Trimble, *supra* note 83, at 489.

¹⁷⁰ See *Bayer Corp. v. Natco Pharma Limited*, OA/35/2012/PT/MUM (Ind. 2012) (where a German pharmaceutical company owned the patented drug "Sorafenib tosylate." This drug was called "Nexavar" and was used to treat advance stages of kidney and liver cancer. Beyers received a license to import the drug to India in 2007; however, the company did not import the drug at all in 2008 and only imported little amount in 2009 and 2010. As a result, because the consumers demand was not being met, Natco was granted a compulsory license to produce the generic form of "Nexavar").

to \$165, allowing nearly 65,000 of the 170,000 people in Brazil receiving free treatment from the government and saving the nation an estimated \$30 million.¹⁷¹ Pharmaceutical companies such as Merck highly criticized the decision by Brazil, stating that the issuance of the compulsory license greatly disincentivize research-based companies from working in Brazil.¹⁷²

Like Brazil, almost all developing countries rely on imported medicine for public health crises. Only a few developing countries have the innovative capabilities to produce new drugs by a process of reverse engineering. In developing nations, medical costs are often out of pocket and a large proportion of the population lives below the poverty line. Thus, stricter intellectual property rights that will also restrict the production and export of cheap generic medicines will have dire consequences for these individuals.

Countries are allowed to provide safeguards for its domestic policies to take measures to protect public health in accordance with the TRIPS Agreement and the Doha Declaration.¹⁷³ Data published by Rebecca Hellerstein in collaboration with the *Campaign for Access to Essential Medicines run by Médecins Sans Frontières (MSF)* shows a new cross-country data set of antiretroviral drugs (ARV).¹⁷⁴ The table below shows the mean and standard deviation of the ARV Prices across all sampled countries. The report states that “the mean price of a capsule is \$0.67...with a standard deviation of \$0.71, indicating significant price dispersion across countries.”¹⁷⁵ Furthermore, the reports show that “given monopolistic and competitive countries’ average per-capita annual incomes of 272 and 1411 dollar, respectively, holding the degree of competition constant one would expect markups, and so prices, be somewhat lower in the former than the latter.”¹⁷⁶

¹⁷¹ *AIDS Drugs: Brazil, Thailand Override Big Pharma Patents, Médecins Sans Frontières*(May 11, 2007), <https://www.msf.org/aids-drugs-brazil-thailand-override-big-pharma-patents>.

¹⁷² *Id.*

¹⁷³ *Opinions on Ethics and Professionalism*, American Academy of Orthopedic Surgeons, <http://www.aaos.org/about/papers/ethics/1209eth.asp>.

¹⁷⁴ Federal Reserve Bank of New York, Rebecca Hellerstein, *What Do Drug Monopolies Cost Consumers in Developing Countries?* Staff Report no. 530 (Dec. 2011).

¹⁷⁵ *Id.* at 2.

¹⁷⁶ *Id.* at 2-3.

	NRTIs				NNRTIs		NRTIs and NRTIs' and	
	Didanosine	Lamivudine	Stavudine	Zidovudine	Efavirenz	Nevirapine	NRTIs' and	All
Summary statistics per capsule	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Average price (\$)	0.46	0.50	0.48	0.29	0.95	1.30	0.64	0.67
standard deviation	(.45)	(.51)	(.69)	(.28)	(.64)	(1.39)	(.78)	(.71)
Regression results per capsule								
Marginal cost (\$)	0.24 (.04)***	0.27 (.03)***	0.15 (.05)***	0.16 (.03)***	0.64 (.15)***	0.57 (.16)***	0.28 (.03)***	0.33 (.03)***
Markup: per-capita GDP (\$)	0.008 (.004)**	0.009 (.005)*	0.012 (.009)	0.003 (.004)	0.015 (.008)**	0.021 (.018)	0.011 (.004)***	0.010 (.003)***
monopoly (\$)	0.16 (.05)***	0.42 (.16)***	0.56 (.26)**	0.35 (.10)***	0.46 (.32)	0.98 (.55)*	0.49 (.20)***	0.50 (.25)**
R^2	0.86	0.89	0.73	0.83	0.79	0.86	0.75	0.73
Per annual dose								
Marginal cost (\$)	350	195	112	120	699	416	255	1125
as share of per-capita GDP								
monopolistic (%)	129	72	41	44	257	153	94	190
competitive (%)	25	14	8	9	50	29	18	37

Table 1: A comparison of costs and markups for antiretrovirals in countries with and without widespread availability of generics. Notes: Starred coefficients are significant at the *10-, **5-, or ***1-percent level. Annual figures marked with an "ns" are derived from daily coefficients that are not significant at the 10-percent level. Sources: Médicins Sans Frontières; World Development Indicators, World Bank; Author's calculations. Per capsule dosages are as follows: Didanosine, 100 mg; Lamivudine, 100 mg; Stavudine, 40 mg; Zidovudine, 100 mg; Efavirenz, 200 mg; Nevirapine, 200 mg.

Compulsory licenses are issued to threaten citizens' wellbeing or a nation's economic standing. Establishing grounds for local working could be used as means of reducing high prices for medicines. In light of TRIPS Article 31 and Doha 5(A), countries are within their rights when issuing compulsory licensing for failure to work locally.

B. Conflict Between TRIPS Article 27 and Paris Article 5

The panel report on the EC-Canada case noted that interpretation of legal ambiguities in WTO agreements should be through the proper application of the Vienna Convention.¹⁷⁷ The counter argument in that case has been that "Article 27(1) is absolute and non-derogable by Article 31, and that any other interpretation would 'violate fundamental precepts of treaty interpretation' notably by reducing Article 27(1) to redundancy or inutility."¹⁷⁸ For this argument, it is important to note that it is against international law's interpretive principle that ideas and words may be assumed or imported into a treaty.¹⁷⁹

This article argues that local working requirements continue to be generally permissible under TRIPS and are not precluded by Article 27. The general provision of non-discrimination provided in Article 27 should be subject to the specific exceptions

¹⁷⁷ Vienna Convention, *supra* note 17, Part III Articles 30-33 (1969).

¹⁷⁸ EC – Canada ¶ 5.36 at 138.

¹⁷⁹ See Champ & Attaran, *supra* note 82, at 368.

contained in Articles 30 and 31 of TRIPS under the notion of *lex specialis derogate legi generali*.¹⁸⁰ Furthermore, Article 2 of TRIPS specifically enumerated articles of the Paris Convention, which were incorporated into the negotiated treaties, and this includes Article 5A, which provided for failure to work as an option for compulsory licensing.¹⁸¹

Additionally, the *travaux préparatoires*¹⁸² of the agreement confirm that local working requirements were not abolished under the TRIPS agreement.¹⁸³ During Uruguay rounds negotiations, three positions on local working requirements were asserted.¹⁸⁴ Developing countries wanted the requirement to work locally as an essential condition for their conferral of patent rights.¹⁸⁵ In contrast, the United States,, seemed to bar any possible obligations or remedy for failure to work locally.¹⁸⁶ Finally, the European communities landed in the middle, proposing that local working should be a permissible exception but not obligated on the patentee.¹⁸⁷ In analyzing all three

¹⁸⁰ See International Law Commission, *Fragmentation of International Law*, http://legal.un.org/ilc/sessions/55/pdfs/fragmentation_outline.pdf (“There are two ways in which law takes account of the relationship of a particular rule to general rule (often termed a principle or a standard). A particular rule may be considered an application of the general rule in a given circumstance. That is to say, it may give instructions on what a general rule requires in the case at hand. Alternatively, a particular rule may be conceived as an exception to the general rule. In this case, the particular derogates from the general rule. The maxim *lex specialis derogat lex generali* is usually dealt with as a conflict rule. However, it need not be limited to conflict”).

¹⁸¹ *Id.*

¹⁸² The Dag Hammarskjöld Library, *What are travaux préparatoires and how can I find them?.*, <http://ask.un.org/faq/14541> (Defining *travaux préparatoires* as “the name used to describe the documentary evidence of the negotiation, discussions, and drafting of a final treaty text. . . . According to the Vienna Convention on the Law of Treaties, these documents can be used to supplement the interpretation of a treaty when the meaning is ambiguous or obscure when reading the treaty alone.”); See also Dörr & Schmalenbach, *supra* note 116, at x (noting in relation to what information and material outside the text of a treaty can be brought into the process of interpreting the treaty... “The most commonly used and most controversial of those [interpretative] means is, of course, the preparatory work of a treaty, which is commonly referred to in its French version as “*travaux préparatoires*”. The restrictive purpose of Art 32 relates above all to that interpretative *topos*, it is labelled a supplementary means of interpretation in order to ensure that recourse to preparatory work is not used as an alternative, autonomous method of interpretation, distinct from the general rule. The main reason for this general scepticism as to the interpretative value of *travaux* seems to be that they are usually seen as being often incomplete and misleading, thus by their nature less authentic than the other elements of interpretation.”)

¹⁸³ Dörr & Schmalenbach, *supra* note 116, at 370.

¹⁸⁴ *Id.*

¹⁸⁵ See GATT Secretariat, *Communication from Argentina, Brazil, Chile, China, Columbia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, and Uruguay*, art. 13, GATT Doc. MTN.GNG/NG11/W/71 (May 14, 1990).

¹⁸⁶ See GATT Secretariat, *Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights, Communication from the United States*, art. 27, GATT Doc. MTN.GNG/NG11/W/70 (May 11, 1990) (stating that the U.S. proposal restricted compulsory licensing to national emergencies and anti-competitive abuses).

¹⁸⁷ See GATT Secretariat, *Draft Agreement on Trade-Related Aspects of Intellectual Property*, art. 26, GATT Doc. MTN.GNG/NG11/W/68 (Mar. 29, 1990) (referencing draft agreement from European

proposals and the fact that TRIPS specifically abolishes local working, it can be interpreted that the parties did not come to a consensus on the abolition of local working requirements.

The issuance of compulsory licensing is already governed by a stringent provision and requires countries to take alternative measures to resolve their needs before issuing a compulsory license. Just as established in TRIPS Article 31, countries should have the liberty of determining the grounds on which they issue compulsory licenses. It is imperative to stress that in considerations of the goals and objective of the TRIPS agreement and the Doha Declaration, local working requirements are consistent with the goal of technology transfer and greater policy space for developing countries to address domestic health crisis.¹⁸⁸

Following this analysis and of TRIPS provisions, it is correct to conclude that the provisions of local working under the Paris Convention remains in force today for all WTO members, as it was incorporated into the TRIPS agreement.¹⁸⁹ This recognition of local working does not have to conflict with furthering the protection and enforcement of intellectual property rights, as patent holders may avoid compulsory licensing for failure to work, at least in India, by justifying it with legitimate reasons, whether economic, legal, or technical in nature.¹⁹⁰

In light of the frequently cited “balance” that is envisioned for the international patent system, this article proposes the following interpretation for local working:

In accordance with the goals dictated in the Doha Declaration to promote greater access to medicines and technology transfer, the parties of this agreement must recognize the option for governments to impose local working provisions into their domestic legislation. Such provisions shall meet the requirements provided by Article 31 of TRIPS. Furthermore, member states shall allow for importation to meet such requirements when (a) domestic conditions do not reasonably allow for local manufacturing, and (b) the patent holder reasonably meets domestic market demands at reasonable conditions. Reasonable market demand, and reasonable conditions, are to be determined on a case by case basis by a competent judicial body, analyzing economic factors, market demand and other arguments presented by the parties involved.

This proposal attempts to reach the coveted balancing between public interest and patent right protections. It is likely the argument will remain in contention until a WTO dispute panel decides the issue.

Communities).

¹⁸⁸ Champ & Attaran, *supra* note 82, at 370.

¹⁸⁹ *Id.* at 372.

¹⁹⁰ *Id.*

CONCLUSION

Re-balancing the rights and obligations of WTO members in light of the public interest remains the focus of negotiations taking place. A balanced approach to the flexibilities of TRIPS, with recognition of societal welfare and incentives for useful art, is needed for all agreements. A balanced intellectual property system can allow for the promotion of access to medicines for developing countries and protection of intellectual property rights for pharmaceutical companies.¹⁹¹

While there is still some dispute as to whether local working requirements are still permitted under TRIPS,¹⁹² it is evident from the discussion above that in general, local working provisions are consistent with the standards enumerated in TRIPS provision and furthered by the Doha Declaration. The real question is what should be permitted by such local working provisions and whether or not importation should be allowed to sufficiently meet the requirements.

It is evident from the arguments proposed by both the public interest advocates, and those who advocate for strengthening of intellectual property rights, that close consideration should be paid to both interests. Access to medicines issues are very much at the forefront of concerns to many developing and least-developed countries. But in order to further development to such medicines, it is imperative that we preserve the incentive to invent that promotes investment into R&D by pharmaceutical corporations.

Finally, any dispute panel presented with resolving the issue of legality and definition of local working requirements should take note of the slippery slope trending in intellectual property towards stricter standards. These standards corrode a government's flexibilities, as envisioned by TRIPS, to provide a policy space to address domestic concerns. The panel must consider what possible impact a denial of local working requirements would have, the message it would send to developing countries presented with the future possibility of entering into multilateral agreements, and the hesitance it could create amongst parties to enter into future multilateral treaties.

¹⁹¹ See Yu, *supra* note 6, at 996.

¹⁹² Adelman, *supra* note 90, at 517.